## *REMARKS*

Claims 21 and 22 are pending in the application.

***Rejection under 35 U.S.C. § 103 Is Traversed***

Claims 21-22 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Clark *et al.* (Aust. Vet J. 1986, Apr; 63(4):107-10) in view of Abe *et al.* (Infection and Immunity, May 1976, p. 1473-1478).

The Examiner states,

> Clark [*et al.*] teach that vaccine compositions contained whole cultures, of killed cells formulated in a mineral oil adjuvant (page 107-108). Clark [*et al.*] teach that vaccine compositions comprising culture supernatants provided the most protection against footrot in cattle (see Abstract and page 109).

Office Action page 4, lines 8-12.

> Clark [*et al.*] do not specifically teach that the whole cells were inactivated by using formaldehyde nor does Clark [*et al.*] teach preventing liver abscesses.

Office Action page 4, last two lines.

> Abe [*et al.*] teach that vaccine compositions comprising formalin killed *Fusobacterium necrophorum* [] protected animals from subsequent challenge doses of *Fusobacterium necrophorum* (page 1473).

Office Action page 5, lines 6-8.

> It would be prima facie obvious [] to use formalin-killed vaccine compositions comprising whole-cell cultures of *Fusobacterium necrophorum* in a method of preventing footrot and liver abscesses in bovine because Clark [*et al.*] has demonstrated that compositions comprising *F. necrophorum*, whole cell cultures are effective in preventing footrot in cattle and Abe [*et al.*] teach that vaccine compositions comprising formalin killed *Fusobacterium necrophorum* protected animals from *Fusobacterium necrophorum* infections (which included clearance of live abscesses).

Office Action page 5, lines 13-20.

To establish a *prima facie* case of obviousness, a reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. *Prima facie* obviousness in the present instance is negated at least because the Clark *et al.* and Abe *et al.*

references, when combined, do not teach or suggest the step (c) of "forming a vaccine by combining said inactivated *Fusobacterium necrophorum* culture with an amount of diluent," where according to steps (a)-(b), "said *Fusobacterium necrophorum* whole cell culture contains the growth medium in which said *Fusobacterium necrophorum* is grown." See Claim 21; emphasis added.

Clark *et al.* teach only three vaccines, none of which contain the growth medium as required by Applicants' claimed invention. (Clark *et al.*, page 107, Materials and Methods, Experimental Design and Procedures, lines 1-13).

The vaccine described by Clark *et al.* as "given to Group 1" does not contain the growth medium at least because this vaccine was prepared by filtering the whole cell culture (*i.e.,* the FnBI cells and the growth medium) using a XM100 A membrane having a MW retention of 100,000. (Clark *et al.*, page 107, Materials and Methods, Experimental Design and Procedures, lines 6-9.) Accordingly, this vaccine does not contain the growth medium at least because the vaccine only contains materials that have a MW of at least 100,000 (*e.g.,* the FnBI cells) and that were present in the growth medium used for growing the specific FnBI strain.

The vaccine described as "given to Group 2" also does not contain the growth medium at least because this vaccine was prepared by sonicating washed concentrated FnBI cells. (Clark *et al.*, page 107, Materials and Methods, Experimental Design and Procedures, lines 8-12). Accordingly, this vaccine does not contain the growth medium at least because the concentrated FnBI cell pellet is washed prior to the sonication step.

Finally, the vaccine described as "given to Group 3" also does not contain the growth medium at least because this vaccine "contained cell-free culture supernatant fluid that had been concentrated 10X using an XM100 A membrane", which has a MW cut-off of 100,000 as mentioned above. (Clark *et al.*, page 107, Materials and Methods, Experimental Design and Procedures, lines 12-14). Accordingly, this vaccine does not contain the growth medium at least because the vaccine, which does not even contain FnBI cells, only contains materials that have a MW of at least 100,000 and that were present in the growth medium used for growing the specific FnBI strain.

Abe *et al.*'s vaccine also does not contain the growth medium as required by Applicants' claimed invention. Abe *et al.* teach immunization with *F. necrophorum* bacteria "grown in PDB

broth for 48 h, at 37 [°C], centrifuged, washed three times with saline and formalized (0.4% formaldehyde in saline)." Abe *et al.*, page 1474, Materials and Methods, Immunization, lines 2-5. Thus, Abe *et al.*'s vaccine does not contain the growth medium at least because the bacteria are washed free of the growth medium prior to formalization.

Accordingly, at least because the Clark *et al.* and Abe *et al.* references, when combined, do not teach or suggest forming a vaccine that contains the growth medium, the combined references fail to teach or suggest all the claim limitations. Therefore, the Examiner has failed to set forth a *prima facie* case of obviousness and the rejection must be withdrawn.

## *CONCLUSION*

Applicants believe that all rejections have been properly traversed.

It is believed that all claims are in condition for immediate allowance. The Examiner is invited to contact the undersigned at (336) 721-3682 with any questions she may have concerning this submission. If any action other than allowance of all pending claims is contemplated, Applicants request that the Examiner contact their undersigned representative to discuss a possible interview.

Respectfully submitted,

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